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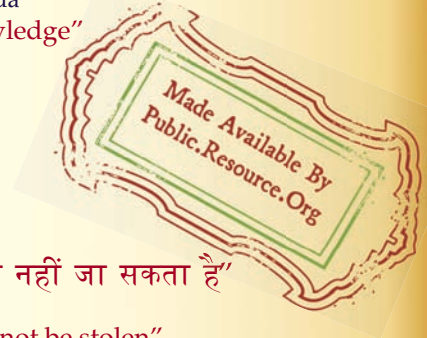
IS 6812 (2003): Knee Joint, Uniaxial for Below Knee Prosthesis [MHD 10: Medical Laboratory Instruments]



“ज्ञान से एक नये भारत का निर्माण”

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“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक
घुटने के जोड़ों, घुटनों से नीचे के कृत्रिम अंग
रोपण के लिए एकाक्ष की विशिष्टि
(दूसरा पुनरीक्षण)

Indian Standard
KNEE JOINT, UNIAXIAL FOR BELOW KNEE
PROSTHESES — SPECIFICATION
(*Second Revision*)

ICS 11.040.40, 11.180.10

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Artificial Limbs, Rehabilitation Appliances and Equipment for the Disabled Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1972. In the first revision more emphasis was given on functional and performance requirements. This revision has been taken up to incorporate certain modifications so as to bring it in line with the modern manufacturing practices. Accordingly in the present revision 2 types of construction of knee joint have been covered and material requirements specified.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final values, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

KNEE JOINT, UNIAXIAL FOR BELOW KNEE PROSTHESES — SPECIFICATION

(*Second Revision*)

1 SCOPE

1.1 This standard specifies the general requirements for the uniaxial knee joint, for below knee prostheses.

2 REFERENCES

2.1 The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

<i>IS No.</i>	<i>Title</i>
1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 Stainless and heat-resisting steels (<i>second revision</i>)
2004 : 1991	Carbon steel forgings for general engineering purposes (<i>third revision</i>)
4398 : 1994	Carbon-chromium steel for the manufacture of balls, rollers and bearing races (<i>second revision</i>)

3 TYPES

3.1 The knee joint shall be of the following types:

- a) *Forged Type Construction* — As shown in Fig. 1.
- b) *Precision Casting Type Construction* — As shown in Fig. 2.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the knee joint shall be as given in Fig. 1 and Fig. 2.

4.2 Inner (medial) joint is the mirror image of the outer (lateral) joint. Two such joints form one set.

5 MATERIAL

5.1 Forged steel shall conform to IS 2004.

5.2 Ball race screw and bearing balls shall conform to IS 4398.

5.3 The joint knee, tower shall be made of stainless steel of Designation 12Cr13, 13Cr13 or 04Cr19Ni9 of IS 1570 (Part 5).

6 FUNCTIONAL REQUIREMENTS

6.1 There shall not be any frictional, jerky or mediolateral moments at the joint.

6.2 Male and female components shall form an angle of 60° or less when closed, and 175° when opened.

7 CONSTRUCTIONAL REQUIREMENTS

7.1 The joint shall have ball race screw and bearing balls with arrangements to replace other ball race screw or balls or both.

7.2 Spider locking washer shall be used to prevent accidental unscrewing.

8 WORKMANSHIP AND FINISH

8.1 All components shall have good finish and be free from mechanical flaws.

8.2 The components, lower and upper, shall be forged/investment cast.

8.3 The forged/investment castings shall be supplied in annealed condition.

8.4 Stainless steel components shall be butted and shall have mall finish.

9 CYCLIC TEST

9.1 The complete assembled unit shall be tested for 20 000 cycles in a suitable testing fixture to simulate the actual conditions. After completion of the test the functioning of the joint shall remain unimpaired.

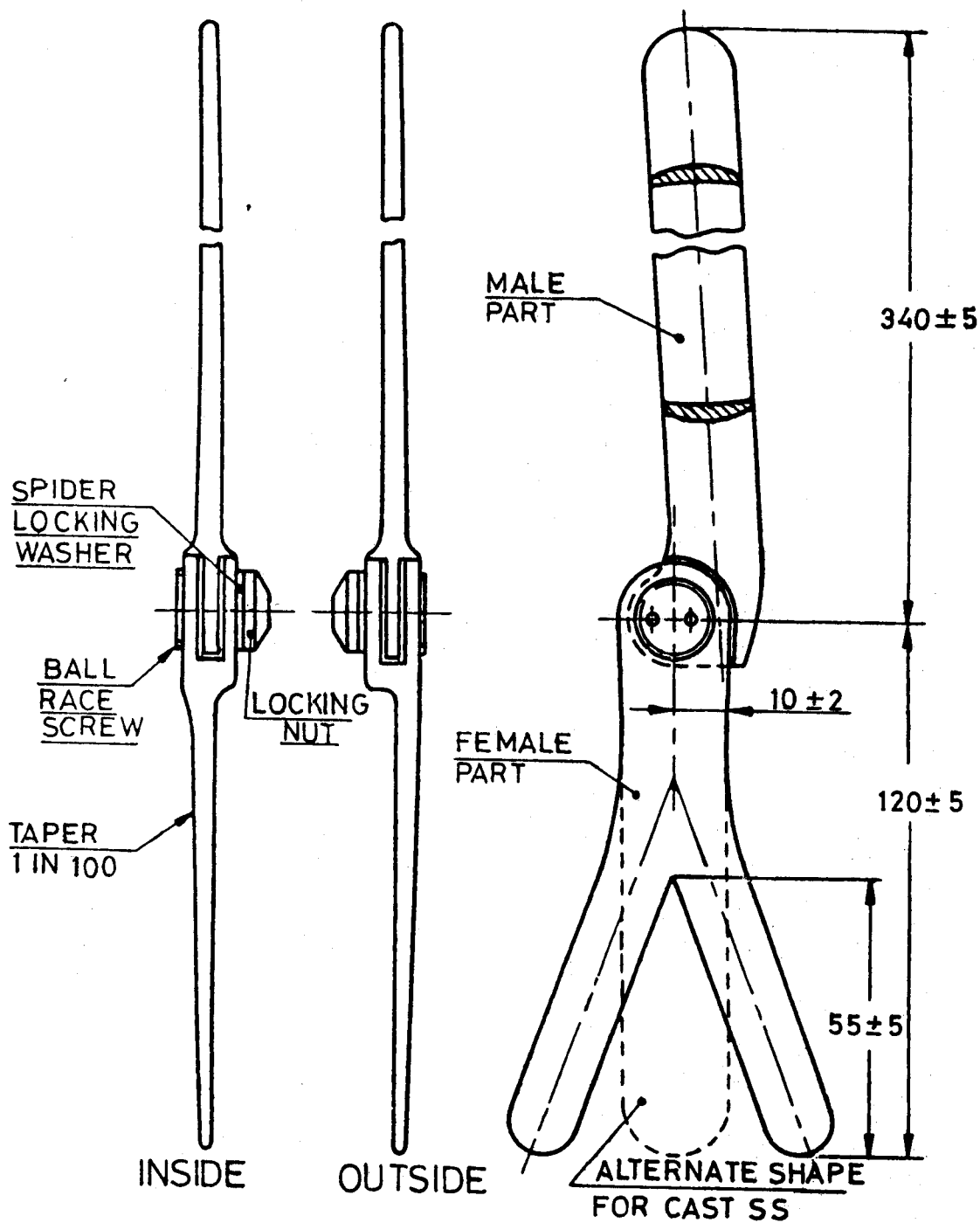
10 MARKING

10.1 The joint shall be clearly marked with the manufacturer's name, initials or recognized trade-mark.

10.2 BIS Certification Marking

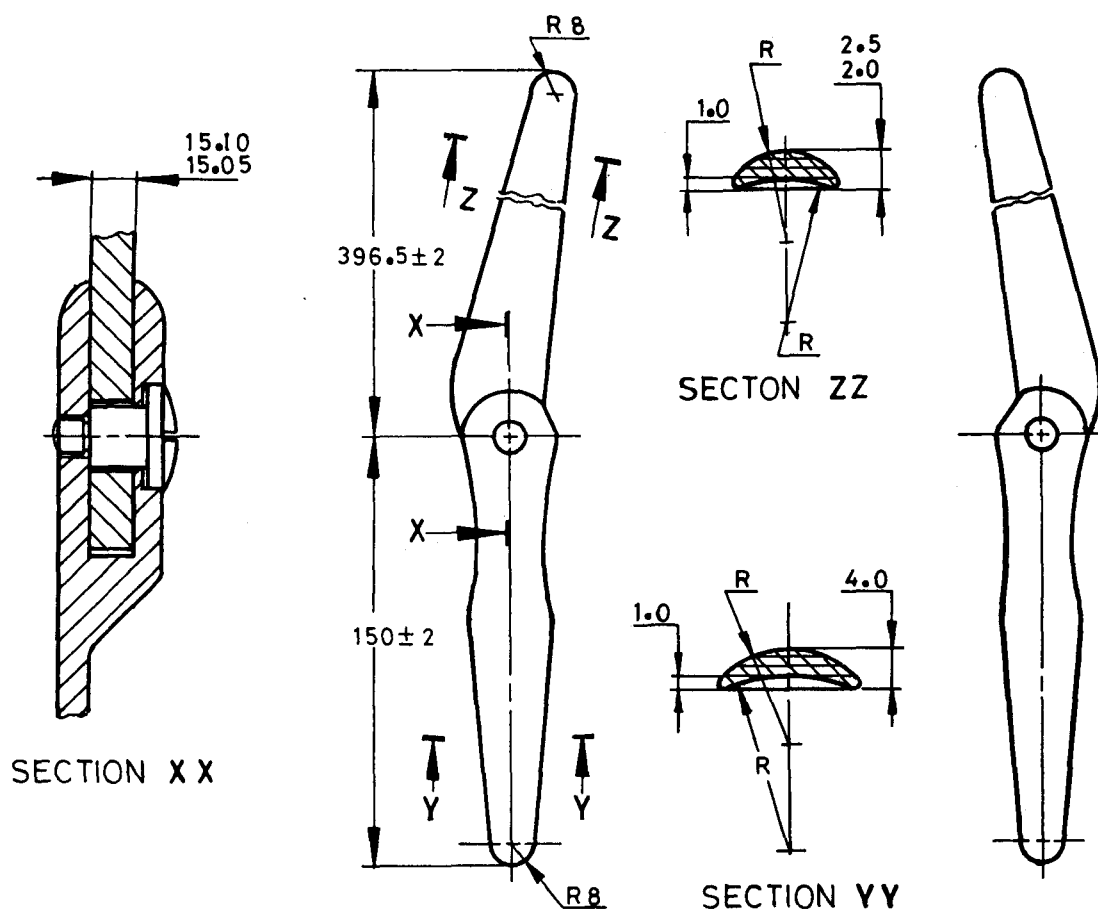
The knee joint may also be marked with the Standard Mark.

10.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards*



All dimensions in millimetres.

FIG. 1 KNEE JOINT UNIAXIAL ASSEMBLY, TYPICAL



All dimensions in millimetres.

FIG. 2 JOINT KNEE FREE

Act, 1986 and the Rules and Regulations made there under. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

11 PACKING

11.1 Packing shall be as agreed to between the purchaser and the manufacturer, however it is recommended that the joint may be packed in the form of a kit.

12 SAMPLING

12.1 A sampling scheme and criteria for acceptance shall be as agreed to between the purchaser and the manufacturer. However a recommended scheme is given in 12.2 to 12.4.

12.2 Lot

All the sets of knee joints of the same type shall be grouped together to constitute a lot. Each lot shall be tested for the requirements of this specification.

12.3 Each set of knee joints, uniaxial for below knee conventional prostheses shall be examined for shape and dimensions (4), functional requirements (6), constructional requirements (7), workmanship and finish (8). All those sets which fail in one or more of the above requirements shall be rejected and only the satisfactory sets of joints shall be accepted.

12.4 For the purpose of cyclic test, one assembled unit shall be randomly selected and be subjected to appropriate test. The sample unit shall pass if the lot is to be accepted under this clause.

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This Indian Standard has been developed from Doc : No. MHD 10 (2735).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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